## REMARKS

### I. Introduction

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 2, 7, 12-15, 18-29, 31-40, 44, and 46-57 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicant reserves the right to pursue the subject matter of the canceled claims in a subsequent continuation application.

Claims 1 5, 6, and 17 are currently being amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1, 3-6, 8-11, 16-17, 30, 41-43, 45, and 58-63 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

### II. Response to Issues Raised by Examiner in Outstanding Office Action

#### a. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1-6, 8-11, 16-17, 41-43, 45, and 58-63 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. Applicant respectfully requests reconsideration and withdrawal of the rejection.

A) Claims 1 and 17

The Examiner objects to the use of the term "does not react with." Applicant has amended the claims to include the term "does not bind with." Since the Examiner has accepted this amendment to clarify claim language in the most recent office response for the first portions of claims 1 and 17, Applicant believes the present amendment should satisfy the Examiner and overcome the objection.

B) Claim 2

The Examiner objects to the use of the word "comprises." The Examiner believes the amendment does not limit the meaning of the claim because in reciting "comprising", [sic] the claim encompasses DCs of a maturational stage between immature and mature, as well as DCs of any other maturational stage. See Office Action, p. 3.

Applicant believes the Examiner is confusing the word "comprises" with the transitional phrase "comprising." The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. See MPEP § 2111.03, 8th ed., rev. 2 (2004).

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA

1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Applicant does not use the transitional phrase "comprising" nor does Applicant use the synonymous terms "including," containing," or "characterized by." Therefore, the claim is not broadened in any way. An understanding of the claim would be evident to one skilled in the art.

Applicant has canceled claim 2, but, as noted below, has amended claim 1 and 17 to include similar language to previously presented claim 2.

C) Claim 5

The Examiner objects to the recitation of "DCs of a restricted size and granularity." In order to clarify the claim, Applicant has amended the claim to include methods for determining size and granularity for a comparison with lymphocytes and monocytes as described in the claim. Based on the specification, a person of ordinary skill in the art could determine if a DC fell within the language of the claim. Support for the amendment is described below. The technique of light microscopy was used in the specification in Example 2, page 58 and Figure 3. Light scatter was used on page 54 and Figure 1 to show size and granularity of M-DC8+ cells. Based on the disclosure and working examples, a person of skill in the art could determine the metes and bounds of the claim. Previous responses to the patent office have included other references providing evidence for the determination of size and granularity by those skilled in the art. Applicant respectfully requests reconsideration and withdrawal of the rejection.

**b. Claim Rejections - 35 U.S.C. § 112, First Paragraph**

Claims 1-6, 8-11, 16-17, 41-43, and 45 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of written description. Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Examiner objects to the phrase "human DCs displaying one or more surface markers of both immature and mature human DCs" (Claims 1 and 17). Applicants believe that a person of ordinary skill in the art would understand the phrase based on the specification, but in order to facilitate prosecution the Applicant has amended claims 1 and 17. The following amendment is not meant as an admission for narrowing the scope of the claim. The amended claims include language clarified above in subsection a) and which has not been specifically objected to for lack of written description support.

The Examiner objects to the generic method comprising the steps of claims 1 and 58-63 and takes the position that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. MPEP § 2163. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Id.

Applicant has fulfilled the requirements for written disclosure by disclosing multiple working examples, actual sequences, functional characteristics, and the deposit of biological materials associated with the claimed inventions. The working examples provide satisfactory disclosure to one skilled in the art that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view

of the species disclosed. Three unique antibodies are disclosed by the Applicant. M-DC8 mAb is extensively described throughout the examples. Figures 9 and 10 provide sequence information regarding the antibody. Experiments describing the purification and testing of the antibody as well as its binding characteristics are detailed. A person of skill in the art would understand the Applicant had possession of an antibody described in the claims.

Applicant also describes two additional antibodies known as D-DC8.1 and D-DC8.2. These antibodies were purified from unique starting materials. They therefore represent a look at multiple species and possibilities for the generation and possession of antibodies associated with the claimed invention. D-DC8.1 was generated using a lymphoma subclone while D-DC8.2 was generated using a complete cell. The complete purification of the antibodies as well as their binding characteristics are disclosed.

Disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004). In addition, the Federal Circuit in *Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) ("*Enzo Biochem II*"), stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." Also, the court held that one might comply with the written description requirement by depositing the biological material with a public depository such as the American Type Culture Collection ("ATCC"). Id. at 970. The court proffered an example of an invention successfully described by its functional characteristics. The court stated:

> For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.

Id.

Based on the court's approach to antibody technology, Applicant believes the above recited claims comply with the written description requirement. The protocol for purifying D-DC8.1 and D-DC8.2 is provided in the specification as well as binding studies for these antibodies. The cell lines for producing the antibodies have been deposited and, therefore, Applicants submit that anyone can acquire the deposited material and determine whether the Applicant possessed the claimed invention. Both *Noelle* and *Enzo Biochem II* envision this type of description as satisfying written description. With three unique examples described in the application, Applicant believes the claims fulfill the written description requirement.

The specification discloses how to produce and analyze antibodies for epitopes in a DC population of a maturational stage between immature and mature DCs. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each member of the species. Antibody technology is a well developed field. The description of the surface antigens of interest on dendritic cells as well as some antibodies for specifically recognizing cells at the claimed maturational stage are provided. The analysis of multiple antibodies is sufficiently clear to provide written description support for possession of antibodies in claims 1 and 58-63.

The Examiner objects to claims 6, 8-9, and 16-17 due to the use of the terms "fragment" or "derivative." The terms fragment and derivative are explained in the context of antibodies. Due to the disclosure on pages 9-11 in the specification, the application discloses well known art for the preparation of fragments of antibodies and derivatives of antibodies. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). By directing the Examiner to the known art in the filed of immunology, Applicant wishes to provide evidence that those skilled in the art knew what the terms "fragment" and "derivative" encompassed. In addition, Applicant notes an explanation for "fragments" is provided in the specification on page 9, last paragraph, and page 10, second paragraph. For example, an antibody fragment may be a Fab, Fv, or scFv fragment. Generally, there is an inverse correlation between the level of skill and knowledge in the art

and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). As noted above in *Enzo Biochem II*, the level of skill in the art has been determined to be "well developed and mature" in the eyes of the Federal Circuit. The meaning of terms such as "fragments" and "derivatives" would have been clear at the time of filing.

Applicants have amended claim 6 to clarify that a derivative must also bind to the provided epitope. See Office Action p. 4, second paragraph. Applicants respectfully request reconsideration and withdrawal of this rejection.

**c. Claim Rejections - 35 U.S.C. § 102**

Claims 1, 6, 10, 16-17, and 41-43 are rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by WO 93/04187. Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Examiner asserts that 93/04187 teaches a monoclonal antibody composition which reacts with human DCs and not other PMBCs, a continuous stable cell line, a method for preparing said antibody, a pharmaceutical composition, a diagnostic composition, and a "kit."

WO 93/04187 discloses mAbs which are highly specific for dendritic cells and which also bind a subpopulation of CD3+ cells. See page 2 of the WO 93/04187 specification. This invention is inconsistent with the claimed invention by Applicant. The application states on page 3, lines 19-23, that human DC-cells are defined by the absence or low expression of a range of lineage specific cell surface antigens which are characteristic, inter alia, for B-cells. CD3 is specifically mentioned as a marker molecule specific for PBMCs other than DCs. In addition, on page 4, line 11, it is mentioned that anti-CD3 is specific for B-cells, i.e. PBMCs other than dendritic cells. Zhou et, al (1995) (See IDS) Table 1 provides additional support for the lack of CD3 in dendritic cells. The antibody of the present invention is therefore not

consistent with WO 93/04187. Claim 1 specifically provides for antibodies that bind dendritic cells but do not bind other PBMCs.

## CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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